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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,414	06/30/2003	David P. Holden	ABIOS.021A	1954

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
850 LINCOLN CENTRE DRIVE
FOSTER CITY, CA 94404

EXAMINER	
SIMS, JASON M	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,414	HOLDEN ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-85* is/are pending in the application.

4a) Of the above claim(s) *22-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19,20,21,84 and 85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 2/6/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 2/6/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 84 and 85, which is acknowledged and have been entered.

Applicant's cancellation of claim 18 in the reply filed 2/6/2007 is acknowledged.

Claims 1-17, 19-21, and 84-85 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

Applicant's arguments and amendment, filed 2/6/2007, with respect to the rejection of claims 1-21 under 35 USC 112 second paragraph have been fully considered and are persuasive. Therefore the rejection has been withdrawn.

Applicant's amendment to the claims filed 2/6/2007 has necessitated the following rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1-17, 19-21, and 84-85 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 contains the wording "selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele" to describe a discrete combination, which has been deemed as vague and indefinite. It is unclear as to what exactly the wording refers. Clearer claim wording is required.

Claims 2-4, 6-17, 19-21, and 84-85 are rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17, 19-21, and 84-85 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-17, 19-21, and 84-85 do not produce a tangible result. Although the amended claims recite a method step of outputting data, the recited method must specify where the data is to be outputted. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a final resulting step of a physical transformation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-9, 10-11, and 16, are rejected under 35 U.S.C. 102(e) as being anticipated by Landers et al (US P/N 6,703,228).

Landers et al. teaches claim 1 at the abstract, col. 25, lines 20-67, col. 3, lines 5-54, col. 6, lines 5-55, col. 26, lines 1-40, col. 30, lines 51-67, col. 31, and col. 32, lines 1-26. The abstract discloses that this invention is a method of genotyping and genomic classification, which represents a method for allelic classification. Landers et al., at cols. 25 and 26, discusses acquiring intensity data from using microarrays from 1,000-10,000s of samples, some of which use several different dyes, which represents acquiring intensity information for a plurality of samples wherein a first intensity is associated with a first allele and a second intensity is associated with a second allele.

Landers et al., at col. 3, lines 5-67, discusses using microarray chips containing thousands of samples and using hybridization reactions to acquire intensity information and determine the presence or absence of a particular SNP. It is known to one of ordinary skill in the art that these hybridization reactions for SNP determination involve comparing signal intensities where a particular intensity is associated with a particular allele, which represents a first allele being associated with a first intensity and a second intensity being associated with a second allele. Additionally, Landers et al., at col. 3, discusses determining allele frequencies of an SNP in a population, which represents identifying one or more data clusters that are associated with a discrete allelic combination and are determined, in part, by comparing the first intensity component relative to the second intensity component. Furthermore, Landers et al., at col. 6 discusses generating genomic patterns for individual genomes based on SNP analysis and frequency and hybridization patterns, which enable a classification of the genome to occur, which represents evaluating intensity information to identify data clusters and each cluster being associated with a particular allele. Landers et al., at col. 31 and 32, discusses using a likelihood model to predict the probability that a sample will have a particular disease classification or that particular data will be linked, which represents generating a likelihood model that predicts probability that a sample resides within a particular cluster and determines a sample and its associated allelic composition.

Landers et al. teaches claims 5-9 at col. 6, lines 4-58, col. 21, lines 7-22, and col. 23, lines 17-41. Landers et al., at col. 21, teaches a definition for a polymorphic region and discusses three possible genotypes for a diploid organism and how studying SNPs

is a good way for genotyping these type of complicated genotypes. Landers et al., at col. 6, discusses generating patterns for SNP alleles in different genomes for genomic classification. In addition, Landers et al., at col. 23, discusses using genotyping to determine phenotypes where homozygous or heterozygous genotypes can contribute to phenotypes, which represents that Landers et al. does genotype different genomes that include homozygous and heterozygous genotypes.

Landers et al. teaches claims 10-11 and 21 at col. 3, lines 25-38. Landers et al. discusses genomic classification based on SNP analysis and the genotyping is done using microarrays.

Landers et al. teaches claim 16 at col. 30, lines 51-67.

Claims 1, 5-9, 10-11, and 16 are rejected as being dependent from a rejected claim.

Response to Arguments

Applicant's arguments filed 2/6/2007 with respect to the rejection of claims under 35 USC 101 have been fully considered but they are not persuasive.

Applicant alleges that the claims recite a method that is concrete, tangible, and useful, including "outputting the allelic classification of each of the plurality of samples."

Applicant's arguments are not found persuasive. Although the amended claims recite a method step of outputting data, the recited method must specify where the data is to be outputted. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or

a memory or another computer on a network, or to a user, or by including a final resulting step of a physical transformation.

Applicant's arguments filed 2/6/2007 with respect to the rejection of claims under 35 USC 102 have been fully considered but they are not persuasive.

Applicant alleges that Landers et al. fails to identically describe a method for allelic classification including features of "evaluating at least the relationship between the first intensity component and the second intensity component for each of the plurality f samples to identify one or more data clusters, each data cluster associated with a discrete combination.

Applicant's argument is not persuasive as Landers et al. at col. 28, lines 1-45 discusses evaluating a relationship between first and second intensity components for each of the plurality for samples. Additionally, Landers et al. at col. 3 discusses analyzing hybridization reactions to acquire intensity information and determine the presence or absence of a particular SNP and determine allele frequencies based on different probes and their intensity information, which reads on evaluating the relationship between different intensities for each of the plurality of samples to identify one or more data clusters where the clusters are associated with different combination of alleles.

Applicant alleges that Landers et al. fails to describe generating a likelihood model that predicts the probability that a selected sample from the plurality for samples will reside within a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample.

Applicant's argument is not persuasive as Landers et al. at col. 32 does disclose a likelihood model that determines SNP classification and determines the probability that a specific allelic combination is tied to a particular disease, which reads on being tied to a particular data cluster.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER